

FORM PTO-1390 (Modified)
(REV 11-2000)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

29988/AX98148

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR

09/869511

INTERNATIONAL APPLICATION NO.

PCT/EP99/09289

INTERNATIONAL FILING DATE

30 November 1999

PRIORITY DATE CLAIMED

28 December 1998

TITLE OF INVENTION

PREPARATIONS CONTAINING ALPHA POLYGLUCANS FOR TOPICAL APPLICATION

APPLICANT(S) FOR DO/EO/US

Holger BENGES, Anette BRUNNER, Jurgen GRANDE, Silke SCHUTH, Gitta BOHM, and Alfred BRAUNAGEL

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☒ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☒ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 20 below concern document(s) or information included:

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
20. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
22. ☒ Certificate of Mailing by Express Mail
23. ☒ Other items or information:

Postal card receipt

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR)
097/869511

INTERNATIONAL APPLICATION NO.
PCT/EP99/09289

ATTORNEY'S DOCKET NUMBER
29988/AX98148

24. The following fees are submitted:

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :

- ☐ Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO **\$1000.00**
- ☒ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO **\$860.00**
- ☐ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO **\$710.00**
- ☐ International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) **\$690.00**
- ☐ International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) **\$100.00**

CALCULATIONS PTO USE ONLY

ENTER APPROPRIATE BASIC FEE AMOUNT =

\$860.00

Surcharge of **\$130.00** for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492 (e)). ☐ 20 ☐ 30

\$0.00

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE
Total claims	15 - 20 =	0	x \$18.00
Independent claims	2 - 3 =	0	x \$80.00
Multiple Dependent Claims (check if applicable)			<input type="checkbox"/>

\$0.00

\$0.00

\$0.00

TOTAL OF ABOVE CALCULATIONS =

\$860.00

☐ Applicant claims small entity status. (See 37 CFR 1.27). The fees indicated above are reduced by 1/2.

\$0.00

SUBTOTAL =

\$860.00

Processing fee of **\$130.00** for furnishing the English translation later than months from the earliest claimed priority date (37 CFR 1.492 (f)). ☐ 20 ☐ 30 +

\$0.00

TOTAL NATIONAL FEE =

\$860.00

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable). ☐

\$0.00

TOTAL FEES ENCLOSED =

\$860.00

Amount to be:
refunded \$
charged \$

- a. ☒ A check in the amount of **\$860.00** to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. _____ in the amount of _____ to cover the above fees. A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. **13-2855**. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

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SIGNATURE

James P. Zeller
NAME

28,491

REGISTRATION NUMBER

June 28, 2001

DATE

09/869511

JC18 Rec'd PCT/PTO 2 8 JUN 2001
PATENT APPLICATIONIN THE UNITED STATES PATENT
AND TRADEMARK OFFICE

Applicants: Bengs et al.)	"EXPRESS MAIL" mailing label No.
)	EL564459376US.
Serial No.: To be assigned)	Date of Deposit: June 28, 2001
)	
Filed: Herewith)	I hereby certify that this paper (or fee) is
(June 28, 2001))	being deposited with the United States
)	Postal Service "EXPRESS MAIL POST
For: PREPARATIONS)	OFFICE TO ADDRESSEE" service
CONTAINING ALPHA)	under 37 CFR §1.10 on the date indicated
POLYGLUCANS FOR)	above and is addressed to: Commissioner
TOPICAL APPLICATION)	for Patents, Washington, D.C. 20231
)	
Group Art Unit: To be assigned)	
)	
Examiner: To be assigned)	
)	Richard Zimmermann
)	

PRELIMINARY AMENDMENTCommissioner for Patents
Washington, DC 20231

Sir:

Please amend this application as follows.

In the Specification:Page 1, immediately following the title, please insert the following heading
and paragraph:CROSS-REFERENCE TO RELATED APPLICATIONThis is the U.S. national phase of International Application No. PCT/EP99/09289
filed November 30, 1999, the entire disclosure of which is incorporated herein by reference.In the Abstract:

Please add an abstract as set forth on the attached sheet.

09869511-022002

IN THE CLAIMS:

Claims 1-13 have been amended as follows:

1. A topical preparation comprising at least one biotechnologically obtained, water-insoluble, linear poly- α -glucan.
2. The topical preparation of claim 1, wherein the poly- α -glucan has a degree of branching of at most 8%.
3. The topical preparation of claim 2, wherein the poly- α -glucan has a degree of branching of less than 4 % in the 6-position, and a degree of branching of at most 2% in the other positions.
4. The topical preparation of claim 1, wherein the poly- α -glucan has a degree of branching of less than 0.5% in the 6-position.
5. The topical preparation of claim 1, wherein the poly- α -glucan is poly-1,4- α -D-glucan.
6. The topical preparation of claim 1, wherein the poly- α -glucan is present in an amount of about 0.5 to about 80% by weight, based on the total weight of the topical preparation.
7. The topical preparation of claim 1, wherein the poly- α -glucan has been obtained biocatalytically.

8. The topical preparation of claim 1, wherein the topical preparation is a cosmetic composition.

9. The topical preparation of claim 1, wherein the topical preparation is a human or veterinary medical preparation for external application.

10. The topical preparation of claim 1, wherein the topical preparation is selected from the group consisting of creams, compact creams, lotions, milks, masks, powders, ointments, ointment bases and soaps.

11. The topical preparation of claim 10, wherein the topical preparation is selected from the group consisting of creams, powders and ointment bases for make-up.

12. The topical preparation of claim 11, wherein the make-up is blusher, eye shadow or lipstick.

13. A biotechnologically obtained, water-insoluble, linear poly- α -glucan.

Please add new claims 14 and 15 as follows:

14. The topical preparation of claim 8, wherein the cosmetic composition is a bodycare composition.

15. The topical preparation of claim 8, wherein the cosmetic composition is a decorative cosmetic.

REMARKS

By the foregoing amendments to the specification, a cross-reference to the parent international application has been provided and the claims have been amended to better conform to U.S. practice and to omit multiple dependencies.

Claims 14 and 15 have been added. Support for claims 14 and 15 is found in claim 8 as originally-filed (i.e., prior to this preliminary amendment).

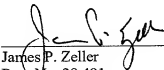
The filing fee has been calculated based on the claims as amended above.
No new matter has been added.

Respectfully submitted,

MARSHALL, O'TOOLE, GERSTEIN,
MURRAY & BORUN

June 28, 2001

By


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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

Page 1 immediately following the title, please insert the following heading and paragraph:

CROSS-REFERENCE TO RELATED APPLICATION

This is the U.S. national phase of International Application No. PCT/EP99/09289 filed November 30, 1999, the entire disclosure of which is incorporated herein by reference.

In the Claims:

Please amend claims 1-13, as follows:

1. (Amended) A topical preparation [which comprises, as essential constituent,] comprising at least one biotechnologically obtained, water-insoluble, linear poly- α -glucan.
2. (Amended) The topical preparation [as claimed in] of claim 1, wherein the poly- α -glucan has a degree of branching of at most 8%.
3. (Amended) The topical [[lacuna] as claimed in] preparation of claim 2, wherein the poly- α -glucan has a degree of branching of less than 4 % in the 6-position, and a degree of branching of at most 2% in the other positions.
4. (Amended) The topical [[lacuna] as claimed in any of the preceding claims] preparation of claim 1, wherein the poly- α -glucan has a degree of branching of less than 0.5% in the 6-position.

5. (Amended) The topical preparation [as claimed in any of the preceding claims] of claim 1, wherein the poly- α -glucan is poly-1,4- α -D-glucan.

6. (Amended) The topical [[lacuna] as claimed in any of the preceding claims] preparation of claim 1, wherein the poly- α -glucan [in the topical preparation] is present in an amount of [from approximately] about 0.5 to [approximately] about 80% by weight, based on the total weight of the topical preparation.

7. (Amended) The topical preparation [as claimed in any of the preceding claims] of claim 1, wherein the [at least one water-insoluble linear] poly- α -glucan has been obtained biocatalytically.

8. (Amended) The topical preparation [as claimed in any of the preceding claims] of claim 1, wherein the topical preparation is a cosmetic composition [, such as bodycare composition or a decorative cosmetic].

9. (Amended) The topical preparation [as claimed in any] of [claims] claim 1 [to 7], wherein the topical preparation is a human or veterinary medical preparation for external application.

10. (Amended) The topical preparation [as claimed in any of the preceding claims] of claim 1, wherein the topical preparation is [chosen] selected from the group consisting of creams, compact creams, lotions, milks, masks, powders, ointments, ointment bases and soaps.

11. (Amended) The topical preparation [as claimed in] of claim 10, wherein the topical preparation is [for decorative cosmetics and is chosen] selected from the group consisting of creams, powders [or] and ointment bases for make-up.

12. (Amended) The topical preparation [as claimed in] of claim 11, wherein the make-up is blusher, eye shadow or lipstick.

13. (Amended) [The use of] A biotechnologically obtained, water-insoluble, linear poly- α -glucan [in a topical preparation].

Please add new claims 14 and 15 as follows:

14. (New) The topical preparation of claim 8, wherein the cosmetic composition is a bodycare composition.

15. (New) The topical preparation of claim 8, wherein the cosmetic composition is a decorative cosmetic.

ABSTRACT OF THE DISCLOSURE

The invention relates to topical preparations containing at least one biotechnologically-produced, water-insoluble, linear poly- α -glucan as an essential constituent of the preparations.

09869511.022002

PREPARATIONS COMPRISING ALPHA-POLYGLUCANS
FOR TOPICAL APPLICATION

Description

- 5
- The present invention relates to a cosmetic or medicinal preparation for topical application, comprising at least one biotechnologically obtained water-insoluble linear poly- α -glucan, in particular a skincare composition.
- 10
- The use of starch-based polysaccharides such as polyglucans for cosmetic purposes has been known since time immemorial.
- Recently, polysaccharide products for cosmetic and therapeutic purposes which have specific profiles of properties have increasingly been
- 15
- developed. For example, H. Eggensperger, M. Wilker in SÖFW Journal, 123rd Volume 8/97, pages 542 to 546, "Multiaktivwirksame Polysaccharide, Teil I – Pilzextrakte [Multiactive Polysaccharides, Part I – Fungus extracts] describes for beta-polyglucans from fungi such as yeasts and carboxymethylated derivatives thereof a high care action for irritated, dry
- 20
- skin.
- Particularly advantageous effects on the skin have been demonstrated for beta-1,3-polyglucans with beta-1,6 linkages, for which, in addition, an immunostimulating action and tumor activity have been observed (loc. cit. F. Züllig et al., loc. cit. pages 535 to 541).
- 25
- Cyclodextrins, cyclic alpha-, beta- or gamma-1,4-oligosaccharides with 6 to 8 glucan units are also being used increasingly for functional skin care since they form inclusion compounds with a large number of active ingredients and care substances and as a result can effect delayed release
- 30
- of these substances at the site of application (U. Citemesi, M. Scalacchitano in Cosmetics and Toiletries magazine, Volume 110, March 1995, pages 53 to 61 "Cyclodextrins in functional dermocosmetics"). Furthermore, it is proposed to use glycogen obtained biotechnologically or obtained from marine molluscs, a highly branched poly-1,4- α -glucan with
- 35
- branches in the 6-position, for cosmetic purposes (M. Pauly, G. Pauly "New Polysaccharides Interest in Care Cosmetology" IN-COSMETICS 1997, Conference Proceedings, pages 417-444, Verlag für chemische Industrie, H.Ziolkowsky GmbH, 1998).

EP-B-0 487 000 proposes an emulsion-like cosmetic composition comprising 15 to 40% by weight of an enzymatically debranched starch, where the enzymatically degraded starch is a linear poly-1,4- α -glucan with 15 to 65 anhydroglucose units.

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Although a large number of products are known for a very wide variety of cosmetic and medicinal uses, there is a continuous need for new improved products. For the preparation of high-value products, it is particularly desirable for basic materials of consistently high quality and with a

10 reproducibly homogeneous profile of properties to be readily available.

Such basic materials can advantageously be used for the preparation of topical preparations for sensitive skin or for medicinal purposes.

15 According to the invention, a preparation for topical use is made available, referred to below also as a topical preparation, which comprises, as essential constituent, at least one biotechnologically produced, linear water-insoluble poly- α -glucan.

20 An essential feature is the use according to the invention of at least one water-insoluble linear poly- α -glucan which has been obtained biotechnologically.

Such poly- α -glucans are distinguished by a high uniformity, purity and
25 simple reproducibility with constant properties. This is of particular importance for high-value cosmetics and medicinal preparations for which a uniformly high quality is not only desired, but also required.

For the purposes of the invention, preparations for topical application are understood quite generally as meaning cosmetic compositions, i.e.
30 bodycare compositions and decorative cosmetics. According to the invention, the term also includes human and veterinary medicinal preparations which are applied externally.

Preparations according to the invention can be creams, compact creams,
35 lotions, masks, powders in any form, e.g. liquid, loose, compact, particulate etc., ointments, ointment bases, soaps etc. for decorative, care or medicinal use.

Examples of decorative cosmetics are creams, powders or bases for make-up, e.g. blusher, eye shadow, lipsticks.

For the purposes of the invention, "biotechnological preparation" means the use of biocatalytic, including biotransformatory, or fermentation processes.

Water-insoluble linear poly- α -glucans prepared by biocatalysis (also: biotransformation) for the purposes of this invention means that the linear polyglucan is prepared by catalytic reaction of monomeric basic building blocks such as oligomeric saccharides, e.g. of monosaccharides and/or disaccharides, by using a "biocatalyst", usually an enzyme, under suitable conditions. In this connection, the expression "in vitro biocatalysis" is also used.

Within the language usage of the invention, water-insoluble linear polyglucans from fermentations are linear polyglucans which are obtained by fermentation processes using naturally occurring organisms, such as fungi, algae, bacilli, bacteria or protists or using non-naturally occurring organisms, but using natural organisms modified using genetic methods of the general definition, such as fungi, algae, bacilli, bacteria or protists, or which can be obtained with the use and assistance of fermentation processes. In this connection, the expression used is also "in vivo biocatalysis".

Examples of such microorganisms are *Pichia pastoris*, *Trichoderma reesei*, *Staphylococcus carnosus*, *Escherichia coli* or *Aspergillus niger*.

Advantageous processes for the biotechnological production are described, for example, in WO 95/31553 or the previously unpublished German patent application from the Applicant with the official file reference 198 27 978.5.

According to the processes described therein, a sucrose solution is treated with amylosucrase, poly-1,4- α -D-glucan and fructose being formed directly with cleavage of the sugar bond.

Further suitable enzymes are polysaccharide synthases, starch synthases, glycol transferases, 1,4- α -D-glucan transferases, glycogen synthases and also phosphorylases.

In contrast to poly- α -glucans which are isolated from natural sources, such as plants, the linear water-insoluble polyglucans obtained here have a particularly homogeneous profile of properties, e.g. with regard to the molecular weight distribution, they contain no, or at worst only very small amounts of, undesired byproducts which have to be separated off at great

expense or could trigger allergic reactions, and can be easily reproduced in an exactly specified manner.

Thus, poly- α -glucans with varying properties such as molecular weights etc. can be obtained as required in a defined and readily reproducible manner.

Although it is also possible to obtain comparatively homogeneous products using chemical or enzymatic debranching, in many cases a remainder of undebranched or only inadequately debranched starting material is left behind, which can only be separated off with difficulty.

Water-insoluble linear poly- α -glucans for the purposes of the present invention are polysaccharides built up from glucans as monomeric building blocks such that the individual building blocks are always linked together in the same manner. Each basic unit or building block defined in this way has exactly two linkages, in each case one to one other monomer. The only exceptions to this are the two basic units which form the start and the end of the polysaccharide. These have only one linkage to one further monomer and form the end-groups of the linear polyglucan.

If the basic unit has three or more linkages, this is referred to as branching. In this context, the number of hydroxyl groups per 100 basic units which are not involved in constructing the linear polymer backbone and form the branches gives the "degree of branching".

According to the invention, the linear water-insoluble poly- α -glucans have a degree of branching of at most 8%, i.e. they have at most 8 branches per 100 basic units. The degree of branching is preferably less than 4% and in particular at most 2.5%.

Particular preference is given to poly- α -glucans whose degree of branching in the 6-position is less than 4%, preferably at most 2% and in particular at most 0.5%, and in the other positions, e.g. in the 2- or 3-position, preferably in each case at most 2% and in particular 1%.

Particular preference is also given to poly- α -glucans whose degree of branching in the 6-position is less than 0.5%.

Of particular suitability for the invention are poly- α -glucans which do not have branches or whose degree of branching is so minimal that it is no longer detectable by traditional methods.

Examples of preferred water-insoluble linear poly- α -glucans are linear poly- α -D-glucans, the nature of the linkage being unimportant, provided there is linearity within the meaning of the invention. A particularly preferred example is poly-1,4- α -D-glucan.

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For the present invention, the prefixes "alpha" or "D" refer solely to the linkages which form the polymer backbone and not to the branches.

10

Biotechnological and, in particular, biocatalytic methods have the advantage that the degree of branching can be set in a controllable manner and, in particular, water-insoluble linear poly- α -glucans can be obtained directly, such as, for example, the preferred poly-1,4- α -D-glucans which do not contain branches, or whose degree of branching is below the detection limit for conventional analytical methods.

15

For the present invention, the term "water-insoluble poly- α -glucan" is understood as meaning compounds which, according to the definition in the German Pharmacopeia (DAB = Deutsches Arzneimittelbuch, Wissenschaftliche Verlagsgesellschaft mbH, Stuttgart, Govi-Verlag, Frankfurt [lacuna] edition, 1987), fall into the categories "slightly soluble", "sparingly soluble", "very sparingly soluble" and "virtually insoluble" compounds, corresponding to classes 4 to 7.

25

In the case of the polyglucans used according to the invention, this means that at least 98% of the amount used, in particular at least 99.5%, are insoluble in water under standard conditions ($T = 25^{\circ}\text{C}/-20\%$, $p = 101325$ Pascal $\pm 20\%$) (corresponding to classes 4 and 5, respectively).

30

For the present invention, preference is given to sparingly soluble to virtually insoluble compounds, in particular very sparingly soluble to virtually insoluble compounds.

35

"Very sparingly soluble" corresponding to class 6 can be illustrated by the following protocol:

One gram of the polyglucan to be investigated is heated in 1 l of deionized water to 130°C at a pressure of 1 bar. The resulting solution only remains stable briefly for a few minutes. Upon cooling under standard conditions, the substance precipitates out again. After cooling to room temperature

and separation by means of centrifugation, at least 66% of the amount used can be recovered, taking into consideration experimental losses.

For the present invention the biotechnologically obtained poly- α -glucan can be used as it is. If desired, it can be subjected to an additional treatment.

Thus, the water-insoluble linear poly- α -glucans can be modified, for example, by chemically modifying the poly- α -glucans by esterification and/or etherification in one or more positions which are not involved in the linear linkage. In the case of the preferred 1,4-linked poly- α -glucans, the modification can take place in the 2-, 3- and/or 6-position.

For the purposes of the invention, modification means that the hydroxyl groups present which are not involved in the linkage are chemically changed. This excludes ring opening of the glucan units, as occurs, for example, during oxidative carboxylation or hydrolysis. Measures for such modifications are sufficiently known to the person skilled in the art.

The poly- α -glucans can be used in the form of "alpha-amylase-resistant" poly- α -glucans, as are described using the example of poly(1,4- α -D-glucan) in the previously unpublished German patent application with the official file reference 198 30 618.0 from the Applicant.

Alpha-amylase-resistant poly- α -glucans can be obtained by preparing a suspension or dispersion of water-insoluble polyglucans and water, heating the suspension or dispersion to a temperature in the range from 50 to 100°C, allowing the resulting paste-like mixture to cool to a temperature in the range from 50°C down to the freezing point, preferably 35 to 15°C, 27 to 22°C, 16 to 0°C or 6 to 2°C, over a period of from 1 to 72 h, preferably 1 to 36 h and in particular 15 to 30 h, and retrograding the paste-like mixture at a temperature which is lower than the temperature of the heated paste-like mixture in a temperature range from 90 to 4°C, and, if desired, drying or dewatering the resulting product.

The poly- α -glucan can also be used as thermoplastic polyglucan obtainable by melting linear water-insoluble polyglucan and adding at least 20% by weight, preferably at least 30% by weight, of a softener such as sorbitol, glycerol, condensation products and oligomers thereof, DMSO,

succinic acid, citric acid monohydrate, malic acid, tartaric acid, etc. at about 170°C.

A description of suitable measures and properties of thermoplastic polyglucans using the example of the preferred linear water-insoluble poly-1,4- α -D-glucan is given in the previously unpublished German patent application with the official file reference 198 52 826, to which express reference is made here.

To improve the incorporability, the thermoplastic poly- α -glucan can be granulated beforehand.

The molecular weights M_w (weight-average, determined by means of gel permeation chromatography relative to calibration with a pullulan standard) of the water-insoluble linear poly- α -glucans used according to the invention can vary within a wide range from 0.75×10^2 to 10^7 g/mol. The molecular weight M_w is preferably in a range from 10^3 g/mol to 10^6 g/mol and particularly preferably from 10^3 g/mol to 10^5 g/mol. A further advantageous range is from 2×10^3 to 8×10^3 . Corresponding ranges apply for the preferably used poly-1,4- α -D-glucan.

The molecular weight distribution or polydispersity M_w/M_n can likewise vary within wide ranges depending on the polyglucan preparation process. Preferred values are from 1.01 to 50, in particular from 1.01 to 15, no values being particularly preferred, e.g. from 1.01 to 2.5.

For the preparation of the topical preparation, it is possible to use a single water-insoluble linear poly- α -glucan or a mixture of two or more thereof.

It is also possible to use mixtures of biotechnologically obtained, water-insoluble linear poly- α -glucan and polyglucans from other sources.

Due to their nature-identity, excellent biocompatibility can be expected for the water-insoluble linear poly- α -glucans used according to the invention.

Depending on the desired use, the topical preparations according to the invention can comprise suitable further ingredients customary for the respective purpose.

Examples of such ingredients as can be used, in particular, also for cosmetic compositions are emulsifiers, oils, waxes, fats or other customary constituents of a cosmetic formulation, such as alcohols, polyols, polymers, foam stabilizers, electrolytes, oils, volatile hydrocarbons, silicone

derivatives or silicone derivatives, active ingredients, humectants, fillers, color pigments, luster pigments, dyes, UV filters, perfume oils, antioxidants, stabilizers, antiinflammatory additives, circulation-stimulating additives, preservatives, bactericides, deodorizing substances, antiperspirants, insect repellants, vitamins, proteins, antifoams, thickeners, emollients, moisturizers and/or humectants, etc.

A list of possible approved ingredients for cosmetic compositions, as can, in principle, also be used for the present invention, is given in the brochure "Kosmetika - Inhaltsstoffe - Funktionen" [Cosmetics - Ingredients - Functions], which has been published by the Industrieverband Körperpflege- und Waschmittel e.V. und dem Fachverband der chemischen Industrie Österreichs, Berufsgruppe Körperpflegemittel, Frankfurt am Main/ Vienna, June 1998.

Medicinal topical preparations generally comprise one or more medicaments in effective concentration.

To differentiate between cosmetic and medicinal use and the corresponding products, reference is made to the prevailing provisions in Germany as are laid down, for example, in the Cosmetics Directive or the Foods and Drugs Act.

It goes without saying that the medicinal preparations may comprise the same ingredients as have been mentioned above by way of example for the cosmetic application, provided they are permitted for medicinal purposes.

In general, the ingredients in question are added to the preparations according to the invention in proportions customary for the respective use purpose.

The linear poly- α -glucans used according to the invention can also be particularly highly effective as matrix material for ingredients to be added to the preparations. For example, cosmetic and/or medicinal active ingredients can be present in adsorbed and/or absorbed form on the poly- α -glucans.

5 In this case, the additives, such as active ingredient etc., may be present as an inclusion in the helix, analogously, for example, to the inclusion compounds formed by the cyclodextrins.

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In addition, an absorbing effect has been observed for the poly- α -glucans used according to the invention.

Because of this absorbing effect, they are also particularly readily suitable as additive in deodorants, body powders such as body talc, for absorbing excess skin sebum e.g. in anti-oil or antiacne products.

- 5 In addition, it has been possible to observe that they are able to reduce skin roughnesses, overall have a calming effect on the skin, and exert a softening and moisturizing action.

Suitable proportions of poly- α -glucan used according to the invention for creams, lotions, make-up, compact creams and the like are in the range
10 from about 0.5% by weight to about 40% by weight, preferably about 2 to about 10% by weight, for powders from about 0.5 to about 80% by weight, for ointments and pharmaceutical ointments, corresponding proportions can be chosen, the proportions in each case being based on the total weight of the preparation in question.

- 15 It goes without saying that, if required, e.g. for particular applications, it is also possible to use more, e.g. up to 100% by weight, or less poly- α -glucan.

- 20 The proportion of poly- α -glucan in the respective preparations is of course governed by the desired effect and/or the particular formulation of the preparation.

The invention is illustrated below by reference to individual examples.

- 25 For Examples 1 to 4, the poly- α -glucan obtained according to Example 5 was used.

Examples 1 and 2 and Comparative Examples 1 and 2

- 30 Preparation procedure for lotion and cream

The composition for the lotion (Examples 1a, 1b and Comparative Example 1) and the cream (Examples 2a, 2b and Comparative Example 2) are given in Table 1.

- 35 Preliminary preparation:

Fatty phase:

Heat emulsifiers and oils to 70°C with stirring. Add preservatives, here parabens, and dissolve with stirring.

Water phase:

- 5 Heat demin. water to 70°C, dissolve remaining constituents with stirring. Disperse poly- α -glucan.

Preservative solution:

Dissolve preservative (imidazolidinylurea) in demin. water.

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Preparation:

Initially introduce fatty phase, $t = 68-70^{\circ}\text{C}$. Add water phase ($t = 68-70^{\circ}\text{C}$) with stirring and homogenize. After the addition, stir and homogenize for 20 min, $t = 65-68^{\circ}\text{C}$.

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Cooling:

to 40°C with stirring.

Add preservative solution and perfume oil and stir and homogenize for 5 min.

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Cool to 30°C with stirring.

The creams and lotions according to the invention felt very pleasant upon application and produced a silky feel on the skin.

The addition of water-insoluble linear poly- α -glucan did not lead to

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whitening on the skin.

Examples 3a and b and Comparative Example 3

Preparation procedure for compact cream make-up

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The composition is given in Table 2.

Preliminary preparation:

Heat lanolin and oils to 80-82°C. Dissolve antioxidant and film former with stirring. Add premelted waxes ($t = 80^{\circ}\text{C}$).

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Preparation:

Add premix of color pigments, titanium dioxide, talc, mica and poly- α -glucan with stirring and homogenization.

Then stir and homogenize for 30 min, $t = 82^{\circ}\text{C}$.

Emptying:

Empty the bulk air-free into suitable containers.

- 5 Compared with the basic formulation, the preparation according to the invention exhibited a reduced wax-like nature.

Examples 4a and b and Comparative Example 4

- 10 Preparation procedure for foundation
The composition is shown in Table 3.
Preliminary preparation:
Heat emulsifier, consistency regulator and oil to 70°C and mix. Add preservative and dissolve with stirring.
- 15 Heat demin. water and propylene glycol to 70°C, dissolve active ingredient and stabilizer with stirring. Aspirate premix of color pigments, titanium dioxide and poly- α -glucan with homogenizer operating. Then stir and homogenize for 30 min.
- 20 Preparation:
Aspirate filtered fatty phase ($t = 70^\circ\text{C}$) with stirring and homogenization and stir and homogenize for a further 10 min, $t = 65^\circ\text{C}$.
- 25 Cooling:
to 40°C with stirring. Add presolution of preservative in demin. water and perfume oil at 40°C. Then stir and homogenize for 10 min.
Cool to 30°C with stirring and homogenization.
- 30 Compared with the base according to the comparative example, the base according to the invention felt considerably more creamy. In addition, an increase in viscosity was observed.

Table 1

Component	Comparison 1	1a	1b	Comparison 2	2a	2b
Sorbitan stearate	1.50	1.50	1.50	1.50	1.50	1.50
Polysorbate 60	2.00	2.00	2.00	2.00	2.00	2.00
Cetyl alcohol				2.50	2.50	2.50
Mineral oil	8.00	8.00	8.00	8.00	8.00	8.00
Decyl oleate	4.00	4.00	4.00	4.00	4.00	4.00
Glyceryl stearate	4.00	4.00	4.00	5.00	5.00	5.00
Dimethicone	0.50	0.50	0.50	0.20	0.20	0.20
Parabens	0.35	0.35	0.35	0.35	0.35	0.35
Demineralized water (aqua)	63.30	63.30	63.30	58.60	58.60	58.60
Allantoin	0.20	0.20	0.20	0.20	0.20	0.20
Propylene glycol	3.50	3.50	3.50	5.00	5.00	5.00
Demineralized water (aqua)	10.00	8.00	5.00	10.00	8.00	5.00
Poly- α -glucan*		2.00	5.00		2.00	5.00
Demineralized water (aqua)	2.00	2.00	2.00	2.00	2.00	2.00
Imidazolidinylurea	0.50	0.50	0.50	0.50	0.50	0.50
Perfume (fragrance)	0.15	0.15	0.15	0.15	0.15	0.15
	100.00	100.00	100.00	100.00	100.00	100.00

* no INCI name

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Table 2

Component (INCI)	Comparison 3	3a	3b
Lanolin	10.10	10.10	10.10
Mineral oil	7.85	7.85	7.85
Castor oil	2.80	2.80	2.80
Octyldodecanol	22.00	20.00	17.00
Isopropyl palmitate	5.00	5.00	5.00
Antioxidant	0.05	0.05	0.05
PVP/eicosane copolymer	0.15	0.15	0.15
Iron oxide	0.68	0.68	0.68
Titanium dioxide *	2.75	2.75	2.75
Talc *	16.07	16.07	16.07
Mica	13.90	13.90	13.90
Poly- α -glucan *		2.00	5.00
Cera microcristallina	9.70	9.70	9.70
Petrolatum	7.65	7.65	7.65
Carnauba	1.30	1.30	1.30
	100.00	100.00	100.00

* no INCI name

Table 3

Component INCI	Comparison 4	4a	4b
Glyceryl stearate	9.00	9.00	9.00
Isopropyl myristate	2.25	2.25	2.25
Cetyl alcohol	1.50	1.50	1.50
Parabens	0.35	0.35	0.35
Demineralized water (aqua)	62.27	62.27	62.27
Allantoin	0.25	0.25	0.25
Xanthan gum	0.30	0.30	0.30
Propylene glycol	8.90	8.90	8.90
Iron oxide	0.68	0.68	0.68
Titanium dioxide *	2.75	2.75	2.75
Demineralized water (aqua)	10.00	8.00	5.00
Poly- α -glucan*		2.00	5.00
Perfume (fragrance)	0.25	0.25	0.25
Demineralized water (aqua)	1.00	1.00	1.00
Imidazolidinylurea	0.50	0.50	0.50
	100.00	100.00	100.00

* no INCI name

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Example 5

In-vitro production of poly-1,4- α -D-glucan in a biocatalytic process using amylosucrase.

- 5 10 l of a 20% strength sucrose solution are added to a sterilized (steam sterilization) 15 l vessel. The enzyme extract, comprising amylosucrase, is added in one portion. The enzyme activity in this experiment is 16 units. The apparatus is provided with a likewise sterilized precision-ground glass
- 10 paddle stirrer. The vessel is sealed and stirred at 37°C. After a period of just a few hours, a white precipitate forms. The reaction is complete after a period of 180 hours. The precipitate is filtered off and, to remove low molecular weight sugars washed five times with water. The residue which remains in the filter is dried at 40°C in a drying cabinet with application of a
- 15 vacuum using a membrane pump (Vacuubrand GmbH & Co., CVC 2). The mass is 685 g (yield 69%).

Example 6

- 20 Characterization of the water-insoluble 1,4- α -D-linear poly-1,4- α -D-glucan from Example 1 synthesized using amylosucrase
- 25 2 mg of the poly-1,4- α -D-glucan from Example 1 are dissolved at room temperature in dimethyl sulfoxide (DMSO, p.a. from Riedel-de-Haen) and filtered (2 μ m filter). Some of the solution is injected into a gel permeation chromatography column. The mobile phase used is DMSO. The signal intensity is measured using an RI detector and evaluated against a pullulan standard (Polymer Standard Systems). The flow rate is 1.0 ml per minute.
- 30 The measurement gives a number-average molecular weight (M_n) of 14,200 g/mol and a weight-average molecular weight (M_w) of 29,500 g/mol. This corresponds to a dispersity of 2.1.

Patent claims

1. A topical preparation which comprises, as essential constituent, at least one biotechnologically obtained water-insoluble linear poly- α -glucan.
2. The topical preparation as claimed in claim 1, wherein the poly- α -glucan has a degree of branching of at most 8%.
3. The topical [lacuna] as claimed in claim 2, wherein the poly- α -glucan has a degree of branching of less than 4% in the 6-position, and a degree of branching of at most 2% in the other positions.
4. The topical [lacuna] as claimed in any of the preceding claims, wherein the poly- α -glucan has a degree of branching of less than 0.5% in the 6-position.
5. The topical preparation as claimed in any of the preceding claims, wherein the poly- α -glucan is poly-1,4- α -D-glucan.
6. The topical [lacuna] as claimed in any of the preceding claims, wherein the poly- α -glucan in the topical preparation is present in an amount of from approximately 0.5 to approximately 80% by weight, based on the total weight of the topical preparation.
7. The topical preparation as claimed in any of the preceding claims, wherein the at least one water-insoluble linear poly- α -glucan has been obtained biocatalytically.
8. The topical preparation as claimed in any of the preceding claims, wherein the topical preparation is a cosmetic composition, such as bodycare composition or a decorative cosmetic.
9. The topical preparation as claimed in any of claims 1 to 7, wherein the topical preparation is a human or veterinary medical preparation for external application.
10. The topical preparation as claimed in any of the preceding claims, wherein the topical preparation is chosen from creams, compact

creams, lotions, milks, masks, powders, ointments, ointment bases and soaps.

11. The topical preparation as claimed in claim 10, wherein the topical
5 preparation is for decorative cosmetics and is chosen from creams, powders or bases for make-up.
12. The topical preparation as claimed in claim 11, wherein the make-up
is blusher, eye shadow or lipstick.
- 10 13. The use of biotechnologically obtained, water-insoluble linear poly- α -glucan in a topical preparation.

00650611-022002

DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY

#6

As a below named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name; I believe that I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled "PREPARATIONS CONTAINING ALPHA POLYGLUCANS FOR TOPICAL APPLICATION," the specification of which was filed on November 30, 1999, as Application Serial No. 09/869,511 and was amended on June 28, 2001. I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above. I acknowledge the duty to disclose to the Patent and Trademark Office all information known to me to be material to patentability as defined in 37 C.F.R. § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. §119 of any foreign application for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

09860366.5	Germany	28 December 1998	Priority Claimed
(Application Serial Number)	(Country)	(Day/Month/Year Filed)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below:

(Application Serial Number)	(Day/Month/Year Filed)
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PCT/EP99/09289	30 November 1999	Pending
(Application Serial Number)	(Day/Month/Year Filed)	(Status-Patented, Pending or Abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY I hereby appoint as my attorneys, with full power of substitution and revocation, to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

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085951-02202

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			Yes No

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PCT/EP99/09289	30 November 1999	Pending
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David A. Gass (38,153)
Gregory C. Mayer (38,238)
Michael R. Weiner (38,359)
William K. Merkel (40,725)

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Second Joint Inventor, if any Anette Brunner	Citizenship Germany
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City (Zip) 91154 Roth	City (Zip) 91154 Roth
State or Country Germany	State or Country Germany
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Third Joint Inventor, if any Jürgen Grande	Citizenship Germany
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State or Country Germany	State or Country Germany
Date <input checked="" type="checkbox"/>	Signature <input checked="" type="checkbox"/>

Fifth Joint Inventor, if any Gitte Böhm	Citizenship Germany
Residence Address - Street Im Burgfeld 243	Post Office Address - Street Im Burgfeld 243
City (Zip) 60439 Frankfurt	City (Zip) 60439 Frankfurt
State or Country Germany	State or Country Germany
Date <input checked="" type="checkbox"/>	Signature <input checked="" type="checkbox"/>

Sixth Joint Inventor, if any Alfred Braunagel	Citizenship Germany
Residence Address - Street Ulrichstrasse 55	Post Office Address - Street Ulrichstrasse 55
City (Zip) 55128 Mainz	City (Zip) 55128 Mainz
State or Country Germany	State or Country Germany
Date <input checked="" type="checkbox"/>	Signature <input checked="" type="checkbox"/>

00000001-00000000

DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name; I believe that I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled **"PREPARATIONS CONTAINING ALPHA POLYGLUCANS FOR TOPICAL APPLICATION,"** the specification of which was filed on November 30, 1999, as Application Serial No. 09/869,511 and was amended on June 28, 2001. I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above. I acknowledge the duty to disclose to the Patent and Trademark Office all information known to me to be material to patentability as defined in 37 C.F.R. §1.56.

I hereby claim foreign priority benefits under 35 U.S.C. §119 of any foreign application for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

19860366.5	Germany	28 December 1998	Priority Claimed
(Application Serial Number)	(Country)	(Day/Month/Year Filed)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below:

(Application Serial Number)	(Day/Month/Year Filed)
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PCT/EP99/09289	30 November 1999	Pending
(Application Serial Number)	(Day/Month/Year Filed)	(Status-Patented, Pending or Abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: I hereby appoint as my attorneys, with full power of substitution and revocation, to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

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Date 06.05.01 <input checked="" type="checkbox"/>	Signature Silke Schuth <input checked="" type="checkbox"/>

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00000001.022002

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(Application Serial Number)	(Country)	(Day/Month/Year Filed)	<input checked="" type="checkbox"/> <input type="checkbox"/>
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503

Fifth Joint Inventor, if any Gitte Böhm	Citizenship Germany
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State or Country Germany	State or Country Germany
Date <input checked="" type="checkbox"/> 6.9.2001	Signature <input checked="" type="checkbox"/> <i>Gitte Böhm</i>

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600

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Date <input checked="" type="checkbox"/> AUG. 29, 2001	Signature <input checked="" type="checkbox"/> <i>Δ P. B. C.</i>

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